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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,356	03/30/2004	Moshe Arkin	27246	4110

7590 03/17/2006

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/812,356	ARKIN ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-207* is/are pending in the application.

4a) Of the above claim(s) *24,43-109,136 and 148-207* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23,25-42,110-135 and 137-147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-207 are pending. Acknowledgement of receipt of applicant's election of Group I and species election of lactic acid as the pH-adjusting agent in the response filed on January 31, 2006 is made. Claims 24, 43-109, 136, and 148-207 are withdrawn from consideration as being drawn to a nonelected invention and/or species. Claims 1-23, 25-42, 110-135 and 137-147 are under consideration in the instant office action.

Election/Restrictions

Applicant's election of Group I in the reply filed on January 31, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademarks LUXIQ® (pg. 3, line 32) and OLUX® (pg. 3, line 32 and pg. 27, lines 5 and 30) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23, 25-42, 110-135 and 137-147 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for foamable pharmaceutical compositions, does not reasonably provide enablement for said compositions devoid of a buffering agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The term "buffering agent" is not defined in the specification. It is noted that independent claims 1 and 110 recite the limitation that the pharmaceutical composition is devoid of a buffering agent. It is also noted that on page 9 of the specification of

the instant application the phrase, "devoid of a buffering agent," is stated. However, it is noted that the Applicant's examples of their invented composition contain lactic acid in an aqueous formulation at a pH of 6.00. At a pH of 6.00, lactic acid would consist of a mixture of lactic acid and its conjugate base, lactate, wherein the majority of the species in solution would be lactate. This determination is based upon the acid dissociation constant (K_a) of lactic acid (1.4×10^{-4}), lactic acid pK_a (~3.8), and the input of the values for the lactic acid pK_a and the pH of the examples in the instant specification into the Hendersen-Hasselbalch equation (see below). Because lactic acid does not dissociate completely, it is appropriately termed a weak acid. Buffers are comprised of a mixture of a weak acid and its corresponding conjugate base (e.g. lactic acid and lactate). See for example, Brown, T. L. et al. *Chemistry: The Central Science, 6th edition*, Prentice Hall: Englewood Cliffs, NJ, 1994, pp. 628-630 and 1016. It is also noted that

$$pH = pK_a + \log([A^-]/[HA])$$

$[A^-]$ is the concentration of the conjugate base of the weak acid.

[HA] is the concentration of the weak acid, HA.

dependent claim 21 further limits independent claim 1 to further comprise at least one humectant (i.e. it may comprise more than one humectant), including lactic acid and various lactate salts, which combined would result in a buffered composition. Therefore, the exemplary compositions of applicant's invention inherently comprise a buffer and applicant's invention is not enabled for foamable pharmaceutical compositions devoid of a buffering agent. Support for the notion that lactic acid is a buffering agent can be found in, for example, Kor et al. (US 2003/0166702) in

[0046] where lactic acid is identified as a buffer; and in Hanna et al. (US 2002/0177624), wherein lactic acid is part of a buffering system (see especially [0035]-[0036]), comprising a combination of acid (e.g. lactic acid) and a hydrogen-accepting substance.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 22, 25-26, 134, and 137-138 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 134 are vague and indefinite because these claims recite the following terms: "hexylene glycol derivative," "sugar derivative," and "starch derivative." It would have been ambiguous to a person of ordinary skill in the art at the time of the instant application what Applicant considered to be derivatives of hexylene glycol, sugar, and starch.

Claims 25-26 and 137-138 are confusing, because these claims depend from claim 1, which recites that the composition is devoid of a buffering agent. However, it is noted that the Markush groups of pH-adjusting agents of claims 25 and 137 comprise weak acids, which do not dissociate completely and would inherently result in the formation of a buffer. Buffers consist of a weak acid and its corresponding conjugate base, for example, lactic acid (i.e. a weak acid) and lactate (the conjugate base of lactic acid). It would have been apparent to a skilled artisan that lactic acid would form a buffering system. See for example, Brown, T. L. et al. *Chemistry: The Central Science, 6th edition*, Prentice Hall: Englewood Cliffs, NJ, 1994, pp. 628-630 and 1016.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 19, 21-22, 27-29, 110-113, and 131-134 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (U.S. Patent No. 5,352,437).

No weight is given to the intended use of products/compositions and instructions on a package are not considered further limitations of a packaged composition.

Nakagawa discloses a **foamable aerosol preparation** for use as the base of cosmetics, **quasi drugs, drugs**, and so forth, which comprises **0.1 to 5 w/v % of a surfactant, 0.05 to 10 w/v % of a lower alcohol and/or a glycol, 3 to 25 w/v % of water, and 60 to 95 w/v % of n-butane gas** (abstract). The term carrier reads on alcohol, glycol, water, and propellant (i.e. butane gas).

Nakagawa discloses a base formulation comprising 0.1 to 5 w/v % of a surfactant, 0.05 to 10 w/v % of a lower alcohol and/or a glycol, 3 to 25 w/v % of water and 60 to 95 w/v % of n-butane gas, and **an active ingredient added thereto** (col. 2, lines 22-25). The composition also includes surfactants selected from a group consisting of various polyoxyethylene derivatives, including polyoxyethylene alkylphenyl ether acetates (col. 2, lines 27-30). The lower alcohol includes **ethanol and isopropanol**. The term "glycol" includes **propylene glycol**, 1,3-butanediol, 3-methyl-1,3-butanediol, dipropylene glycol, tripropylene glycol, glycerin, polyoxyethylene polyoxypropylene glycol and **polyethylene glycol** (col.2, lines 54-59).

Nakagawa discloses that the active ingredient may comprise an anti-inflammatory steroid, including **diflucortone, diflorasone diacetate, and clobetasol propionate**. The active may also be non-steroid type anti-inflammatory agents such as methyl salicylate, glycol

salicylate, and ketoprofen (col. 3, lines 10-23). In Examples, 5-9 and 11-13, Nakagawa discloses compositions wherein the active agent is present in amounts ranging from 0.05 w/v% to 2.0 w/v%. Example 11 is a composition comprising **clobetasol propionate in an amount of 0.05 w/v %**.

Claims 1-19, 21-23, 25-40, 110-131, 133-135, and 137-145 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. (WO 96/27376).

This rejection is being made based on the instant specification lacking enablement for foamable pharmaceutical compositions devoid of a buffering agent. No weight has been given to the phrase "devoid of a buffering agent." No weight is given to the intended use of products/compositions and instructions on a package are not considered further limitations of a packaged composition.

Jones **discloses foamable pharmaceutical composition comprising a corticosteroid active substance, a quick break foaming agent, a propellant**, and a buffering agent. The quick break foaming agent comprises an **aliphatic alcohol, water, a fatty alcohol, and a surface-active agent** (i.e. surfactant) (abstract).

Jones discloses preferred quick break foaming compositions comprising an **aliphatic alcohol in amounts of 40-90% w/w, water in amounts of 10-40% w/w, at least one fatty alcohol in amounts of 0.5-10% w/w, and a surfactant in amounts of 0.1-15% w/w**. The fatty alcohol may be selected from **cetyl, stearyl, lauryl, myristyl, and palmityl alcohols, and mixtures of cetyl and stearyl alcohol are particularly preferred**. The aliphatic alcohols may be chosen from **methyl, ethyl, isopropyl, and butyl alcohols** and mixtures of two or more

thereof. The surfactants may be chosen from **ethoxylated sorbitan stearate, palmitate, oleate, nonyl phenol ethoxylates, and fatty alcohol ethoxylates, and mixtures of two or more thereof**. **Polysorbate 60**, a mixture of partial stearic esters of sorbitol and its anhydrides copolymerized with approximately 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides, is preferred. The surfactant enhances the fatty alcohol solubility in the system and foam formation (sentence bridging the bottom of page 2 and page 3 and all of page 3).

Jones discloses on the top of page 4 that the propellant may be chosen from conventional aerosol propellants, including **propane, butane**, dichloro difluoro methane, dichloro tetrafluoro ethane, octafluoro cyclobutane, **and mixtures of two or more thereof**. In the middle of **page 4, Julie discloses that other additives may be used and that it is preferred to add a** humectant in an amount **from 0.10-10.0 % w/w**, wherein the preferred humectant is **propylene glycol**. Other suitable humectants include **glycerine, panthenol, and sorbitol**.

Jones discloses a listing of suitable corticosteroids deliverable using her invention (pgs. 4-5) including, **clobetasol propionate and betamethasone dipropionate**. The corticosteroid is preferably present in an **amount of 0.01-1.0 % w/w** (pg. 5). The corticosteroid species listed in the Markush group of claim 27 of the instant application **are the same** corticosteroid species disclosed by Jones on pages 4-5 of WO 96/27376.

Jones discloses that it is necessary to buffer the composition and states that suitable buffering agents include acetic acid/sodium acetate, citric acid/sodium citrate, and phosphoric acid/sodium phosphate, wherein **the composition pH is maintained in the range 3.0-6.0** (pg. 5, last paragraph of said page).

Jones discloses an exemplary composition on page 8, comprising **betamethasone valerate (0.12 % w/w), cetyl alcohol (1.10 % w/w), octadecan-1-ol (0.50 % w/w), polysorbate 60 (0.40 % w/w), ethanol (57.59 % w/w), purified water (33.69 % w/w), propylene glycol (2.00 % w/w), citric acid anhydrous (0.073 % w/w), potassium citrate (0.027 % w/w), and butane/propane (4.30 % w/w).** Octadecan-1-ol is a stearyl alcohol.

Jones discloses that the composition of her invention **may be contained in and dispensed from a container** capable of withstanding the pressure of the propellant gas and having an appropriate valve/nozzle for dispensing the composition as a foam under pressure (bottom of page 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagawa et al. (USPN 5,352,437) (USPN '437).

Nakagawa does not anticipate claim 30, because the disclosure of USPN does not disclose a concentration of a corticosteroid between 0.05 and 0.2 weight %, based on the total weight of the composition.

The teachings of Nakagawa have been set forth above.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to modify the amount of corticosteroid in a foamable pharmaceutical formulation based on the teachings of Nakagawa, because Nakagawa teaches a concentration of clobetasol propionate of 0.05 weight/volume (w/v) %. Furthermore, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed

parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Claims 2-18, 20, 25-26, 31, 34-37, 39-42, 114-128, 132, 135, 137-139, and 141-144 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagawa et al. (USPN 5,352,437) (USPN '437) as applied to claim 30 above, and further in view of Quigley Jr. et al. (U.S. Patent No. 6,075,056).

The teachings of Nakagawa have been set forth above.

Nakagawa lacks the teaching of a carrier comprising at least one fatty alcohol, at least one hydrocarbon alcohol, at least one surface-active agent, and water.

Quigley teaches stable topical formulations comprising an antifungal agent and an **antiinflammatory steroid** are disclosed, useful for treating fungal diseases and their related inflammation (abstract).

Quigley teaches that the antifungal compositions may comprise pharmaceutically acceptable excipients including solvents, emollients, humectants, and emulsifiers. Solvents may include **propylene glycol, hexylene glycol, polyethylene glycol**, etc. Emollients may include **lower fatty acid esters, propylene glycol, cetyl alcohol, stearyl alcohol**, etc. (col. 2, lines 53-67).

Quigley teaches that the **pH is adjusted where necessary to a pH of about 3.5-7.0**, using an acid (e.g. **hydrochloric acid, phosphoric acid**) or a base (e.g. diethanolamine, triethanolamine, sodium hydroxide) or known-buffering agents (col. 3, lines 1-4).

Quigley teaches a variety of exemplary antiinflammatory steroids suitable for use in his invented compositions, **including betamethasone dipropionate, clobetasol propionate,**

diflorasone diacetate, fluocinonide, halcinonide, fluocinolone acetonide, hydrocortisone butyrate, and methylprednisolone. The steroid is present in the composition in amounts varying **from about 0.001% to about 5% w/w** (col. 4, lines 55-67 and col. 5, lines 1-58).

Quigley teaches that his compositions may be provided in a variety of forms, including **foams**, liquid solutions, powders, etc. (col. 7, lines 31-35). Quigley also teaches several exemplary compositions, see, for example, Tables A, B, C, and E. Table C is especially significant, as the composition exemplified therein comprises **water (qs; i.e. from ~ 9.5 % to 93% w/w), cetyl alcohol (1-10 % w/w), stearyl alcohol (1-10 % w/w), polysorbate 60 (1-15 % w/w), and steroid (0.01-2.5 % w/w)**.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Nakagawa and Quigley, because Quigley teaches stable topical formulations comprising an antifungal agent and an anti-inflammatory steroid. Quigley's compositions are useful in the treatment of fungal diseases and the inflammation resulting from said diseases. A skilled artisan would have had a reasonable expectation of success upon combination of the prior art references, because both Nakagawa and Quigley teach compositions comprising corticosteroids, water, polysorbate 60, and a lower alcohol (i.e. ethanol). Regarding the non-CFC propellant, it would have been apparent to a skilled artisan to use a propane/butane/isobutane mixture, because Nakagawa teaches the use of n-butane as a propellant. Propane, a linear three-carbon hydrocarbon, is obvious over n-butane, a linear four-carbon hydrocarbon, because these compounds are homologous, differing only by one methylene group (i.e. $CH_3CH_2CH_3$ vs. $CH_3CH_2CH_2CH_3$). Isobutane is obvious over n-butane, because it is a structural isomer of n-butane and both compounds have the same chemical formula (C_4H_{10}).

Regarding the amount of propellant, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Claims 20, 41-42, 132, and 146-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones **et al. (WO 96/27376).**

This rejection is being made based on the instant specification lacking enablement for foamable pharmaceutical compositions devoid of a buffering agent. No weight has been given to the phrase "devoid of a buffering agent."

The disclosures/teachings of Jones have been set forth above.

Jones does not anticipate claims 41-42 and claims 146-147, because Jones lacks an express teaching of a composition comprising propane/butane/isobutane as a non-CFC propellant in a concentration between about 4 and about 5 weight percentages, based on the weight of the total composition. Regarding claims 41 and 147, Jones does not disclose/teach a composition pH of about 6.5.

It would have been apparent to a person of ordinary skill in the art at the time of the instant invention that the disclosures/teachings of Jones regarding a propellant comprising a non-CFC propellant are obvious over the propellant recited in claims 41-42 and 146-147 of the

instant specification, because Jones teaches a non-CFC propellant comprising propane and butane. Isobutane is a structural isomer of butane, and is therefore obvious over butane. It would have been apparent to a skilled artisan to use a propane/butane/isobutane mixture for this reason. Regarding a pH of about 6.5, the pH of a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal pH required for compositions comprising pH-sensitive corticosteroids to obtain a stable composition. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of a composition's pH would have been obvious at the time of applicant's invention. Regarding the non-CFC propellant, it would have been apparent to a skilled artisan to use a propane/butane/isobutane mixture, because Jones teaches the use of propane/butane as a propellant. Isobutane is obvious over butane, because it is a structural isomer of butane and both compounds have the same chemical formula (C_4H_{10}). Therefore, it would have been apparent to a skilled artisan that a mixture of propane/butane is obvious over a mixture of propane/butane/isobutane.

Double Patenting

Applicant is advised that should claim 32 be found allowable, claim 33 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing,

despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 33 is a composition claim, which recites the intended use of a foamable composition packaged in a packaging material. Because no weight is given to the intended use of compositions, claim 33 substantially duplicates claim 32.

Other Matter

It was noted that the word "isobutane" was misspelled as "isobutene" in claims 41 and 146, line 11 in both claims. Appropriate correction is required.

Conclusion

The specification is objected. The claims under consideration in the instant office action (i.e. 1-23, 25-42, 110-135 and 137-147) are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER